

**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:	)	
	)	
<b>Malin ERNEBRANT et al.</b>	)	Group Art Unit: 1616
	)	
Application No.: 10/591,233	)	Examiner: Abigail L. FISHER
	)	
Filed: May 7, 2007	)	Confirmation No.: 9327
	)	
For: A MEDICAL SOLUTION, A METHOD	)	<b><u>VIA EFS-WEB</u></b>
FOR PRODUCING SAID MEDICAL	)	
SOLUTION AND USE THEREOF	)	

**Attention: Mail Stop Appeal Brief-Patents**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**APPEAL BRIEF UNDER BOARD RULE § 41.37**

In support of the Notice of Appeal filed July 22, 2011, further to Board Rule 41.37, and further to the Notice of Panel Decision from Pre-Appeal Brief Review dated August 23, 2011, Appellant presents this brief and enclose herewith the fee of \$540.00 required under 37 C.F.R. § 41.20(b)(2).

This Appeal responds to the March 22, 2011, final rejection of claims 1-25 and 29-33, and to the Notice of Panel Decision from Pre-Appeal Brief Review dated August 23, 2011.

If any additional fees are required or if the enclosed payment is insufficient, Appellants request that the required fees be charged to Deposit Account No. 06-0916.

## **Table of Contents**

Real Party In Interest.....	3
Related Appeals and Interferences .....	4
Status Of Claims.....	5
Status Of Amendments.....	6
Summary Of Claimed Subject Matter .....	7
Grounds of Rejection to be reviewed on Appeal.....	8
Arguments .....	9
Conclusion.....	18
Claims Appendix to Appeal Brief Under Rule 41.37(c)(1)(viii) .....	19
Evidence Appendix to Appeal Brief Under Rule 41.37(c)(1)(ix) .....	24
Related Proceedings Appendix to Appeal Brief Under Rule 41.37(c)(1)(x) .....	25
Attachment: Declaration under 37 C.F.R. § 1.132 of Malin Ernebrant previously submitted on January 21, 2011.	

**Real Party In Interest**

Gambro Lundia AB is the real party in interest, as reflected in the Recordation of Assignment dated May 7, 2007, recorded at Reel: 019368, Frame: 0080.

### **Related Appeals and Interferences**

There are currently no other appeals or interferences, of which Appellants, Appellants' legal representative, or Assignees are aware, that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

### **Status Of Claims**

Claims 1-25 and 29-33 are currently pending. The Preliminary Amendment filed August 31, 2006, amended original claims 1-25, cancelled original claim 26, and added new claims 27-30. In the Amendment filed January 21, 2011, claims 27 and 28 were cancelled without prejudice or disclaimer, claims 1, 2, 6, 8, 19, and 21-23 were amended, and new claims 31-33 were added.

Claims 1-25 and 29-33 are finally rejected by the Examiner, and Appellants hereby appeal the rejection of these claims. Pursuant to 37 C.F.R. §41.37(c)(1)(iii) and (viii), the attached Appendix contains a clean copy of the claims involved in this Appeal.

### **Status Of Amendments**

All amendments have been entered. No outstanding amendments under 37 C.F.R. § 1.116 have been filed.

### **Summary Of Claimed Subject Matter**

The claimed invention relates to medical solutions that may be used in, for example, hemodialysis, hemofiltration, hemodiafiltration, peritoneal dialysis, dialysis within renal intensive care, and liquids for substitution/infusion containing a buffering substance. Specification as-filed, page 1, lines 1-13.

More specifically, Appellant found that a medical solution comprising, *inter alia*, a first single solution comprising bicarbonate and carbonate in such proportions that a partial pressure of carbon dioxide in the first single solution is of the same order of magnitude as a partial pressure of carbon dioxide in the atmosphere, and having a pH of 10.1 - 10.5; that when mixed with a second single solution comprising an acid, and having a pH of 1.0-1.5, form a final solution at a pH of 7.0-7.6, which results in medical solutions with good stability and biocompatibility. Specification as-filed, page 2, ll. 30-32; see *also* claim 1.

The present application contains one independent claim, claim 1, which recites:

A medical solution comprising:

a first single solution comprising bicarbonate and carbonate in such proportions that a partial pressure of carbon dioxide in the first single solution is of the same order of magnitude as a partial pressure of carbon dioxide in the atmosphere, and has a pH of 10.1 - 10.5; and

a second single solution comprising an acid,

wherein said first and second single solutions are mixed after terminal sterilization to form a final solution, wherein said second single solution has a pH of 1.0 - 1.5 and said final solution has a pH of 7.0 - 7.6.

**Grounds of Rejection to be reviewed on Appeal**

A. Claims 1-7, 11-14, 16, 17, 20, and 24 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,296,242 ("Zander") in view of U.S. Patent No. 6,309,673 ("Duponchelle"). Final Office Action dated March 22, 2011, pages 2-10.

B. Claims 8-10, 15, 18, 19, 21-23, 25, and 29-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zander, Duponchelle, and further in view of International Patent Application Publication No. WO 01/89478 ("Linden"). *Id.* at pages 10-14.

Appellant appeals each of these grounds of rejection.

C. The Final Office Action also provisionally rejected claims 1-7, 11-14, 16, 17, 20, and 24 under the doctrine of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-11, 14-17, 20, and 21 of U.S. Application No. 11/658,001. *Id.* at pages 18-19. Appellant requests abeyance of the double patenting rejection until such time as the Examiner allows the claims. M.P.E.P. § 804.02.



## Arguments

### **A. Claims 1-7, 11-14, 16, 17, 20, and 24 are patentable over Zander and Duponchelle**

#### **1. The Examiner's Rejection**

The Examiner contends that Zander discloses “two separately stored single solutions to be combined prior to use wherein one is bicarbonate-free acid solution and the other is a bicarbonate-containing alkaline solution,” but does not “teach the instantly claimed pH values.” (Final Office Action dated March 22, 2011 at pages 4-5 (emphasis omitted).) Relying on Duponchelle, the Examiner concludes that “it would have been obvious . . . to manipulate the pH of the starting materials to achieve the desired final pH . . . [s]ince both Zander and Duponchelle are directed to the same type of compositions . . . .” (Final Office Action at pages 15-16.) The Examiner also contends that “Zander recognizes the desire to have the magnitude of the carbon dioxide of the solution match that of the atmosphere. Therefore, manipulation to achieve this matching would have been obvious.” (Advisory Action dated June 13, 2011 at page 2). Appellant respectfully disagrees and traverses the rejection.

#### **2. The Legal Standard**

Obviousness is a legal question based on underlying facts. (*Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1356 (Fed. Cir. 2008)). Those factual determinations include (1) “the scope and content of the prior art,” (2) “the level of ordinary skill in the art,” (3) “the differences between the claimed invention and the prior art,” and (4) “evidence of secondary factors, also known as objective indicia of non-obviousness.” (*Eisai*, 533 F.3d at 1356 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966))). “While the sequence of these questions might be reordered in any

particular case, the [*Graham*] factors continue to define the inquiry that controls.” (*KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007)). In addition, when reviewing the differences between the claimed invention and the prior art, M.P.E.P. § 2143.03 requires “all words of a claim be considered.” Therefore, the Examiner is required to make “a searching comparison of the claimed invention - including all its limitations - with the teachings of the prior art.” (*In re Wada and Murphy*, Appeal 2007-3733, citing *In re Orchiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) and *CFMT v. Yieldup Intern. Corp.* 349 F.3d 1333, 1342 (Fed. Cir. 2003)).

Moreover, the Supreme Court has maintained the requirement that the prior art provide some reason or motivation to arrive at the claimed invention. (*KSR*, 550 U.S. at 401 (“[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.”)) However hindsight cannot replace motivation in the prior art to make the claimed invention. (*KSR*, 550 U.S. at 421 (cautioning against “the distortion caused by hindsight bias” and “arguments reliant upon *ex post* reasoning” in determining obviousness)).

In addition, the law provides that knowledge of a problem and motivation to solve it are entirely different from a motivation to combine *particular references to reach the particular claimed invention*. *In re Omeprazole Patent Litigation*, 536 F.3d 1361, 1380-81 (Fed. Cir. 2008)(finding that it was not obvious to make a particular formulation when there are multiple paths for solving the problem, even for one of ordinary skill in the art who recognizes the problem).

### **3. The Examiner failed to establish a *prima facie* case of obviousness**

**i. Zander and Duponchelle fail to teach all the elements of the claims**

In the instant case, the combination of Zander and Duponchelle, fail to disclose or suggest all the claim limitations, including and in particular, “a first single solution comprising bicarbonate and carbonate in such proportions that a partial pressure of carbon dioxide in the first single solution is of the same order of magnitude as a partial pressure of carbon dioxide in the atmosphere.” (See e.g., claim 1). Because the Examiner has not and cannot point to any teaching in Zander or Duponchelle, alone or in combination, that suggests this claimed element, Appellant submits that the Examiner failed to establish a *prima facie* case of obviousness.

As an initial matter, the Examiner contends that “while the claims do recite the equilibrium of partial pressure, the claims **do not require any specific proportions.**” (Advisory Action at page 2) (emphasis added). This is incorrect. Claim 1 recites, *inter alia*, “a first single solution comprising bicarbonate and carbonate **in such proportions** that a partial pressure of carbon dioxide in the first single solution is of the same order as a partial pressure of carbon dioxide in the atmosphere.” (emphasis added). Based on the specification, one of ordinary skill in the art would understand the term “in such proportions” to mean a particular proportion of bicarbonate/carbonate that allows the first single solution to be in equilibrium with the partial pressure of carbon dioxide in the atmosphere. (As-filed Specification at page 3.) In order for the first single solution to be in equilibrium with the partial pressure of carbon dioxide in the atmosphere, **there must be a greater concentration of carbonate than bicarbonate in the first single solution.** (See e.g., Examples 1-40 in the as-filed specification.)

The Examiner improperly disregards this element of claim 1. (*In re Lowry*, 32 F.3d 1579,1582 (Fed. Cir. 1994) (the “Patent and Trademark Office (PTO) must consider all claim limitations when determining patentability of an invention over the prior art.”)). The Examiner, however, must still show that all of the elements of the claims are taught in the prior art in order to arrive at the present invention. Yet, neither Zander nor Duponchelle teach or suggest the specific proportion of carbonate/bicarbonate necessary to equilibrate with the carbon dioxide in the atmosphere in order to obtain a first single solution and an overall medical solution having a stable pH.

The Examiner contends that “Zander teaches liquids which have a carbon dioxide partial pressure which corresponds to that of atmospheric air do not change their overall carbon dioxide content which makes them more stable.” (Advisory Action at page 2). This is a mischaracterization of Zander’s teachings. Zander discloses that its final solutions contain a CO<sub>2</sub> partial pressure corresponding to the **physiological blood plasma value**. (Zander at col. 2, ll. 35-40). More importantly, Zander does **not indicate any** value of CO<sub>2</sub> partial pressure for its individual bicarbonate solution, much less that it “compris[es] bicarbonate and carbonate in such proportions that a partial pressure of carbon dioxide in the [bicarbonate solution] is of the same order of magnitude as a partial pressure of carbon dioxide in the atmosphere.” (See e.g., claim 1). The extent of Zander’s teachings is merely that its solutions “can be stored in air, without requiring special equipment for preventing a diffusing off or in of carbon dioxide.” (Zander at col. 2, ll. 1-4). Nowhere does Zander link the proportion of bicarbonate and carbonate present in the bicarbonate solution that would allow it to be

in equilibrium with the partial pressure of carbon dioxide present in the atmosphere. And, as explained further below, Duponchelle prefers alkaline solutions only containing bicarbonate. Accordingly, the combination of Zander and Duponchelle fail to teach all the limitations of the claims.

**ii. Zander and Duponchelle provide one of ordinary skill in the art no reasonable expectation of success to arrive at the claimed invention.**

The Examiner's failure to consider all of the claim limitations notwithstanding, the Examiner also failed to show that one of ordinary skill in the art with knowledge of Zander and Duponchelle would have had a reasonable expectation of success of arriving at the claimed invention through modifying or combining these references. For example, as discussed above, Zander never makes any affirmative statements linking the proportions of bicarbonate and carbonate present in the bicarbonate solution equilibration with the partial pressure of carbon dioxide present in the atmosphere. Although Zander teaches in its summary of the prior art that "DE-OS 3 514 346" teaches "certain concentrations of alkali carbonate and alkali bicarbonate" such that the "overall CO<sub>2</sub> content" does not change after contact with atmospheric air, Zander fails to indicate how the concentrations of bicarbonate/carbonate relate to whether its bicarbonate solution will equilibrate with the partial pressure of carbon dioxide present in the atmosphere. (Zander at col. 1, ll. 55-65).

Zander's failure to link the specific proportion of bicarbonate/carbonate present in the bicarbonate solution that would allow it to be in equilibrium with the partial pressure of carbon dioxide present in the atmosphere is reflected in Zander's disclosure that its bicarbonate solutions all contain a **greater concentration of bicarbonate than carbonate**. (Zander at Abstract). Zander teaches that the 19.1 mmol of alkali

bicarbonate and 6.1 mmol of alkali carbonate is required so that its final solution has a bicarbonate concentration of 24 mmol/l - "the immediate buffer bicarbonate in physiological concentration." (Zander at col. 3, ll. 47-65). Zander stresses the importance of maintaining that particular proportion of bicarbonate and carbonate (19.1 mmol of alkali bicarbonate and 6.1 mmol of alkali carbonate) even if the volume of finished solution (combined acid and bicarbonate solutions) changes. (Zander at col. 4, ll. 7-22).

Based on Zander's teachings, one of ordinary skill in the art would have been motivated to utilize a bicarbonate solution comprising a **greater concentration of bicarbonate than carbonate** as emphasized in Zander in order to reach the physiological bicarbonate concentration. Thus, one of ordinary skill in the art would not have reasonably expected to succeed in obtaining the claimed invention by modifying the teachings of Zander. Instead, one of ordinary skill in the art would have been led away from the claimed invention requiring a proportion of bicarbonate/carbonate that allows it to equilibrate with the partial pressure of carbon dioxide present in the atmosphere; i.e., a **greater concentration of carbonate than bicarbonate**. (M.P.E.P. § 2141.02(VI)).

Duponchelle does not remedy the deficiencies of Zander, and in fact, leads one of ordinary skill in the art even further away from the pending claims. Duponchelle teaches that it is "preferable to have **all buffer available as bicarbonate**." (Duponchelle at col. 3, ll. 42-58.) (emphasis added). Thus, Duponchelle actually teaches away from the claimed medical solutions and Zander, which include both bicarbonate and carbonate in a particular proportion. While the Examiner alleges

motivation in Zander and Duponchelle because these references generally recognize problems associated with maintaining a stable bicarbonate solution (Advisory Action at 2), Appellant contends that Zander and Duponchelle instead would have led one of ordinary skill in the art to a different solution than the claimed invention. (See Examination Guidelines Update: Developments in the Obviousness Inquiry After *KSR v. Teleflex*, 75, Fed. Reg. 53,643, 53,695 (Sept. 1, 2010) (citing *In re Omeprazole Patent Litigation*, 536 F.3d 1361 (Fed. Cir. 2008) (explaining that one of ordinary skill in the art would have chosen a different modification for the enteric subcoating of omeprazole even if she or he had recognized the problem))).

Neither reference recognizes that a particular proportion of bicarbonate/carbonate enables it to be in equilibrium with the partial pressure of carbon dioxide present in the atmosphere. According to M.P.E.P. 2144.05, “[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.” Thus, the Examiner’s assertion that “manipulation to achieve [the proportion of bicarbonate/carbonate] would have been obvious,” is merely hindsight-driven since neither Zander nor Duponchelle recognize that it is the proportion of bicarbonate/carbonate that allows the bicarbonate solution to have the same magnitude of partial pressure of carbon dioxide as that of the atmosphere.

Moreover, Zander and Duponchelle fail to recognize the benefit of the particular proportion of bicarbonate/carbonate to the overall stability of the pH of the combined solution. For example, as demonstrated in the Declaration under 37 C.F.R. §1.132 of

co-inventor Malin Ernebrant ("Declaration") submitted in the Response dated January 21, 2011, the stability of a bicarbonate solution containing an approximate 1:6 ratio of bicarbonate to carbonate resulted in a stable pH over a period of 17 days. (Declaration at page 3, Table 4.) Therefore, it is the criticality of the proportion of carbonate/bicarbonate that allows the first single solution to be in equilibrium with the partial pressure of carbon dioxide in the atmosphere which subsequently allows the pH of the first single solution and overall medical solution to be stable over time. Evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness. (M.P.E.P. § 716.02(a)(II)). Accordingly, this evidence is relevant to the issue of obviousness and must be considered. (M.P.E.P. 2141(II)).

Without hindsight knowledge of the specifically claimed proportion of bicarbonate/carbonate, one of ordinary skill would not have known what concentrations of bicarbonate and carbonate to utilize in any effort to result in a bicarbonate solution that is in equilibrium with the partial pressure of carbon dioxide present in the atmosphere. Rather, they would have been led away from a proportion that enables it to be in equilibrium with the partial pressure of carbon dioxide present in the atmosphere. The Examiner's conclusion of obviousness therefore seek to reconstruct the claimed inventions from the prior art using hindsight bias, which is legally impermissible. (*KSR*, 550 U.S. at 421; *Ortho-McNeil*, 520 F.3d at 1364-65). Accordingly, Appellants respectfully request that this rejection be withdrawn.

**B. Claims 8-10, 15, 18-19, 21-23, 25 and 29-33 are patentable over Zander Duponchelle, and Linden**



The Examiner contends that Zander fails to teach “the addition of a third or fourth single solution,” and “does not specify that the sterilization is heat sterilization at a temperature of at least 100°C,” and relies on Linden to remedy these deficiencies. (Final Office Action at page 10). However, as discussed in Section A above, the Examiner failed to show that the combination of Zander and Duponchelle teach or suggest all of the claim limitations and also failed to show that one of ordinary skill in the art had any reasonable expectation of success in arriving at the claimed medical solutions based upon modifying Zander. Linden does not remedy the deficiencies of Zander and Duponchelle. Instead, Linden is similar to Duponchelle in that if Linden contains a bicarbonate solution at all, it does not contain carbonate. (Linden at Examples 1-5.) Nowhere does Linden teach or suggest a particular proportion of carbonate/bicarbonate in its medical solutions. Thus, this combination of references does not establish a *prima facie* case of obviousness of claims 8-10, 15, 18-19, 21-23, 25 and 29-33. Accordingly, Appellants respectfully request that this rejection be withdrawn.

### **Conclusion**

For the reasons given above, pending claims 1-25 and 29-33 are allowable and withdrawal of each of the Examiner's rejections is respectfully requested.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: September 22, 2011

By: /Aaron L. Parker/  
Aaron L. Parker  
Reg. No. 50,785

**Claims Appendix to Appeal Brief Under Rule 41.37(c)(1)(viii)**

1. (Previously Presented) A medical solution comprising:  
  
a first single solution comprising bicarbonate and carbonate in such proportions that a partial pressure of carbon dioxide in the first single solution is of the same order of magnitude as a partial pressure of carbon dioxide in the atmosphere, and has a pH of 10.1 - 10.5; and  
  
a second single solution comprising an acid,  
  
wherein said first and second single solutions are mixed after terminal sterilization to form a final solution, wherein said second single solution has a pH of 1.0 - 1.5 and said final solution has a pH of 7.0 - 7.6.
2. (Previously Presented) A medical solution according to claim 1, where said first single solution has a pH of 10.3.
3. (Previously Presented) A medical solution according to claim 1 or 2, wherein said second single solution has a pH of 1.3.
4. (Previously Presented) A medical solution according to claim 3, wherein the second single solution comprises HCl.
5. (Previously Presented) A medical solution according to claim 1, wherein the medical solution further comprises one or more osmotic agents.
6. (Previously Presented) A medical solution according to claim 5, wherein said one or more osmotic agents are chosen from: glucose, glucose polymers, glycerol, xylitol, fructose, amino acids, peptides, proteins, amino sugars, N-acetyl glucose amine (NAG), and combinations thereof.
7. (Previously Presented) A medical solution according to claim 5, wherein said one or more osmotic agents are arranged in said second single solution

before said second single solution is mixed with said first single solution to form the final solution.

8. (Previously Presented) A medical solution according to claim 5, further comprising a third single solution, and wherein said one or more osmotic agents are arranged in said third single solution, prior to the formation of the final solution.

9. (Previously Presented) A medical solution according to claim 8, further comprising a fourth single solution, and wherein said one or more osmotic agents are arranged in said fourth single solution.

10. (Previously Presented) A medical solution according to claim 9, wherein said one or more osmotic agents in said third and/or fourth single solution comprise glucose and/or glucose polymers giving rise to glucose degradation products during terminal sterilization and/or storage, and wherein said third and/or fourth single solutions comprise an acid and have a pH of at least 1.8 and at most 2.6.

11. (Previously Presented) A medical solution according to claim 1 or 5, wherein the medical solution further comprises one or more electrolytes.

12. (Previously Presented) A medical solution according to claim 11, wherein said one or more electrolytes comprise one or more of the ions of sodium, calcium, potassium, magnesium, and/or chloride.

13. (Previously Presented) A medical solution according to claim 11, wherein said one or more electrolytes are arranged in said first single solution, prior to the formation of the final solution.

14. (Previously Presented) A medical solution according to claim 11, wherein said one or more electrolytes are arranged in said second single solution, prior to the formation of the final solution.

15. (Previously Presented) A medical solution according to claim 9, further comprising one or more electrolytes, and wherein said one or more electrolytes are arranged in said third single solution and/or said fourth single solution, prior to the formation of the final solution.

16. (Previously Presented) A medical solution according to claim 1, wherein the first and second single solutions are provided in first and second compartments in a multi-compartment bag before being mixed to form the final solution.

17. (Previously Presented) A method for producing a medical solution according to claim 1, said method comprising:

providing said first and second single solutions in separate compartments; and thereafter

terminally sterilizing said first and second single solutions.

18. (Previously Presented) A method according to claim 17, wherein said step of terminally sterilizing comprises heat sterilization and/or radiation sterilization.

19. (Previously Presented) A method according to claim 17, wherein said step of terminally sterilizing comprises heat sterilization at a temperature of at least 100°C.

20. (Previously Presented) A method according to claim 17, wherein said first and second single solutions, after terminal sterilization, are mixed to form a final solution.

21. (Previously Presented) A method according to claim 31, wherein said first, second, and third single solutions, after terminal sterilization, are mixed to form a final solution.

22. (Previously Presented) A method according to claim 32, wherein said first, second, and fourth single solutions, after terminal sterilization, are mixed to form a final solution.

23. (Previously Presented) A method according to claim 32, wherein said first, second, third, and fourth single solutions, after terminal sterilization, are mixed to form a final solution.

24. (Previously Presented) A method according to claim 17, wherein the first and second single solutions are provided in first and second compartments in a multi-compartment bag before being mixed to form the final solution.

25. (Previously Presented) A multi-compartment bag comprising the medical solution according to one of claims 1, 8, or 9.

Claims 26-28 (Canceled).

29. (Previously Presented) A method according to claim 21, wherein the first, second, and third single solutions are provided in first, second, and third compartments in a multi-compartment bag before being mixed to form the final solution.

30. (Previously Presented) A method according to claim 23, wherein the first, second, third, and fourth single solutions are provided in first, second, third, and fourth compartments in a multi-compartment bag before being mixed to form the final solution.

31. (Previously Presented) A method for producing a medical solution according to claim 8, wherein the first, second, and third single solutions are provided in first, second, and third compartments in a multi-compartment bag before being mixed to form the final solution.

32. (Previously Presented) A method for producing a medical solution according to claim 9, wherein the first, second, third, and fourth single solutions are provided in first, second, third, and fourth compartments in a multi-compartment bag before being mixed to form the final solution.

33. (Previously Presented) A method for producing a medical solution according to claim 32, wherein the first, second, and third single solutions, after terminal sterilization, are mixed to form a final solution.

**Evidence Appendix to Appeal Brief Under Rule 41.37(c)(1)(ix)**

Declaration under 37 C.F.R. § 1.132 of Malin Ernebrant previously submitted on  
January 21, 2011.



**Related Proceedings Appendix to Appeal Brief Under Rule 41.37(c)(1)(x)**

There are no related Appellate proceedings or decisions to be cited in this case.